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Evidence summary for lateral flow devices (LFD) in relation to care homes

Published 23 December 2020

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This publication is available at https://www.gov.uk/government/publications/evidence-on-the-accuracy-of-lateral-flow-device-testing/evidence-summary-for-lateral-flow-devices-lfd-in-relation-to-care-homes

Key message

Rapid turnaround lateral flow tests are appropriate to use in care homes as an adjunct to risk reduction.

Rapid turnaround lateral flow tests enable care homes to use them frequently with results within 30 minutes, which is important in reducing risk.

Testing will not eliminate risk and must be used in conjunction with personal protective equipment (PPE) and infection prevention and control (IPC) measures to support residents to see loved ones as safely as possible This document provides a summary of evidence for care homes on lateral flow device (LFD) testing of visitors for SARS-CoV-2 (the virus that causes COVID-19) using lateral flow technology on entry to the care homes. A visitor is defined as any relative or friend wishing to visit a resident, or any visiting professional who is not a healthcare professional (for example, a hairdresser).

This summary follows the release of visitor testing guidance (https://www.gov.uk/government/publications/coronavirus-covid-19-lateral-flow-testing-of-visitors-in-care-homes) that supports friends and relatives to visit care home residents and provides clarity on the available evidence to support safe visiting as part of our overall approach to promote the health and wellbeing of care home residents.

Friends and relatives tested immediately before their visit can demonstrate they are likely to be free of risk of transmitting COVID-19 by having an LFD negative result. Testing must be done directly before the visit takes place and must be undertaken in combination with other infection prevention and control measures.

Summary of the benefit of LFD testing

Testing is one way of minimising the risk associated with visiting a care home. Testing should be undertaken alongside the recommended IPC measures, including the use of PPE. Testing is not a panacea, but if used appropriately along with other risk mitigation measures, testing reduces the risk of introducing the virus into the care home.

LFDs deliver a rapid assessment – in 30 minutes – of whether someone is likely to be infectious or not. This is very quick compared to other routinely available testing options (for example, the median turnaround time for other testing options in the most recent week data available (19 November to 25 November 2020) was 41 hours) and provides the ability to limit infection spread earlier than with PCR testing. We trialled both laboratory-based PCR and point of care LFD tests in our pilot of visitor testing. For the homes in the pilot who used PCR testing, several practical challenges were identified, for example, visitors struggling to complete PCR testing at home. Further details on the pilot are provided in the preliminary findings section.

Visits benefit the health and well-being of most residents and lack of contact with relatives can be very detrimental in some cases. Visits are also often extremely important for the wellbeing of the visitor, for example for couples who have been together for many years.

Key summary points

- Evaluations from Public Health England and the University of Oxford (https://www.ox.ac.uk/sites/files/oxford/media_wysiwyg/UK%20evaluation_PHE%20Porton%20Down%20%20University%20of%20Oxford_final.pdf) show LFD tests are accurate and sensitive enough for specific case uses within the community setting.
- Extensive testing has shown that LFDs are suitable for use in care homes, where they can help to identify people who are most likely to spread the virus further and help prevent transmission of the disease from staff and visitors.
- It must be emphasised that LFD testing is a risk reduction intervention only. It is critical for visitors to wear PPE and follow infection control methods to keep their loved ones, other residents and staff as safe as possible at all times.
- It is impossible to eliminate risk entirely. Therefore, it is important to achieve the right balance between minimising the risk of infection transmission and the clear benefits to the mental and physical health of residents resulting from visits.

Evidence detail

Summary evidence on the accuracy of LFD testing

In August 2020, the Department of Health and Social Care commissioned Public Health England and the University of Oxford to rapidly identify the most promising LFDs.

More than 130 types of LFD have been assessed and 20,545 evaluations completed. These assessments are ongoing, but one LFD has been prioritised based on performance, the ‘Innova SARS-CoV-2 Antigen Rapid Qualitative Test’.

8,774 validation tests have been performed to date to assess the Innova device.

LFDs are effective at detecting a high viral load in an individual and registering an appropriate positive result. These are people who are thought to be the most infectious.

It is, however, still possible that the test can produce a ‘false positive’ – where someone receives a positive test result even though they do not have the virus.

The accuracy of a test result is determined by several factors:

- sensitivity of a test is a measure of how good the test is at detecting true positive cases
- specificity is a measure of how good the test is at detecting true negative cases
- prevalence is a measure of how many positive cases there are in a population at any one given time

If the population being tested has 0.5% prevalence and the specificity of the antigen LFD test is 99.5% then:

- a test with 50% sensitivity would detect 25 true positive cases, 25 false negatives (people who would be positive on PCR but negative on the LFD) and 50 false positive cases per 10,000 people tested

- with 70% sensitivity you will have 35 true positive cases, 15 false negatives on antigen LFD and 50 false positive cases per 10,000 people tested
- with 90% sensitivity you will have 45 true positive cases, 5 false negatives and 50 false positive cases on antigen LFD per 10,000 people tested

Ongoing review in real time for the 'Innova SARS-CoV-2 Antigen Rapid Qualitative Test' (https://www.ox.ac.uk/sites/files/oxford/media_wysiwyg/UK%20evaluation_PHE%20Porton%20Down%20%20University%20of%20Oxford_final.pdf) shows that the test had a specificity of 99.68% (that is, a false-positive rate of 0.32%), an overall sensitivity of 76.8%, and a sensitivity of over 95% for those with high viral loads.

It should be noted that the preliminary report from the joint PHE Porton Down and University of Oxford SARS-CoV-2 test development and validation cell found the sensitivity of the 'Innova SARS-CoV-2 Antigen Rapid Qualitative Test' dropped from 79% when used by laboratory scientists compared to 73% when used by trained healthcare staff compared to 58% when used by self-trained members of the public. This means there is a higher chance of false negatives when the tests are used by self-trained users until they develop more experience. Many care home members of staff are experienced at performing swabbing and testing and will be doing this on a regular basis.

Preliminary data from the University of Liverpool (https://www.gov.uk/government/publications/innova-lateral-flow-sars-cov-2-antigen-test-accuracy-in-liverpool-pilot-preliminary-data-26-november-2020) which showed a sensitivity of 48.9% was reassessed through recategorisation by cycle thresholds which led to a sensitivity improvement of circa 10%. This means a more accurate estimate of the sensitivity from the Liverpool pilot is circa 58.9%. In addition, the difference between expert reviewers administering the test and other non-clinical testers administering the test disappeared over the 2-week period – which suggests training is a key factor in ensuring higher sensitivity from the LFDs. While further work is undertaken to understand the evidence on sensitivity, it is important that LFD is used in conjunction with other IPC measures.

As part of the pilot deployment of LFDs for mass testing, a subset of individuals tested with LFD have also been tested with PCR. Various datasets from this roll out have been examined by Porton Down and Oxford test centres, none to date have shown a statistically significant difference in LFD performance when compared with the PCR test for individuals with a high viral load.

Lateral flow devices – summary of process

Lateral flow device testing involves the processing of nasal swabs, throat swabs, or sputum (saliva or mucus) samples. The device detects a protein (antigen) produced by the virus at its most infectious stage. If present in the person's sample, a coloured line appears on the device. This uses a well-established technique called immunochromatography, which draws the sample along the device in a similar way to a home pregnancy test kit.

The swab sample is added to a fluid in the test kit. This fluid acts as an extraction buffer and is optimised to release viral antigens from the specimen if they are present. During the test analysis, these antigens migrate along the strip in the lateral flow device, binding to anti-SARS-CoV-2 (the virus that causes COVID-19) antibodies located in the strip. The antibodies are linked to coloured particles. The presence of a coloured band in the test region indicates a positive result for the SARS-CoV-2 viral antigens, while its absence indicates a negative result. In general, it takes up to 20 minutes for a positive result to appear. The manufacturer's guidance is to wait a full 30 minutes to confirm that a result is negative.

Training in handling and analysis of the samples, including relevant principles of infection prevention and control, will be provided to all operators at each care home. The LFD should only be performed on people who are asymptomatic. If a prospective visitor is symptomatic, the care home manager should advise them to seek a PCR test (https://www.gov.uk/get-coronavirus-test).

The care home visitor testing guidance (https://www.gov.uk/government/publications/coronavirus-covid-19-lateral-flow-testing-of-visitors-in-care-homes) provides clarity on full process.

It should be noted that a negative result does not rule out SARS-CoV-2 (the virus that causes COVID-19) infection and there can be false negative results. This is why it is so important to abide by infection prevention and control measures within the care home.

Preliminary findings from the evaluation of care home visitor testing pilot November 2020

In November 2020, a visitor testing pilot was conducted from 16 November to 28 November 2020 with 20 care homes from 3 local authority areas in the low prevalence areas of Cornwall, Devon and Hampshire. The pilot was designed to identify the most effective testing service for visitors and service improvements for further expansion.

The pilot tested visitors with either PCR or LFD tests, of which 15 care homes piloted using LFD tests and 5 care homes piloted using PCR tests.

To understand the end user experience and identify service improvements to the visitors testing service we conducted pilot research involving interviews, observations and working group sessions with the pilot care homes. We also monitored the number of results recorded and tests registered and undertook a quality assurance process in the 15 LFD pilot homes.

Overall, pilot feedback for the LFD service was positive and homes found the process of testing visitors using LFD straightforward albeit time consuming. Visitors, residents and staff were all very emotional at the joy brought to them by having visits. Care home staff spent between 30 minutes to 1 hour testing each visitor. This included 20 to 30 minutes to inform about testing, gain consent, administer the test, registration then 20 to 30 minutes waiting for result and communicating the result to the visitor. During the pilot, homes were hosting between 2 to 7 visits a day, with a clear link to the size of home. The LFD pilot care homes only tested one visitor at a time due to spatial constraints.

The research team identified some additional user needs that would help to improve the service further including notably:

- additional video or pictorial guidance on the whole process would be helpful
- a lot of time and organisation was involved in preparing for LFD testing and space constraints were a challenge particularly for smaller homes. Care homes had to spend time working out where they could test and setting up the testing in order to minimise contact with visitors and streamline the process
- pilot homes found administering the LFD test straightforward. However, some visitors did require support with swabbing, for example, the elderly or those with accessibility needs. The pilot care homes were supportive of providing this support
- all homes found the results registration process simple, although most homes were required to digitally register on behalf of visitors, thus increasing the administration time for care home staff

All pilot LFD homes were also asked to report results of LFD testing on the 'log results app' and perform dual swabs on staff during their regular PCR testing to measure concordance for quality assurance (QA) for up to 30 swabs. The results of this were:

- 315 LFD tests were registered
- 314 tests were negative, and 1 test was positive
- one positive LFD was recorded which returned a negative confirmatory PCR result
- there were no LFD void results
- quality assurance concordance swabbing process identified 100% concordance on 155 tests (155 negative PCR and 155 negative LFD) taken. This means that both PCR and LFD tests returned the same result
- average number of visitor tests a day was 4 tests per day
- the data quality of registered data was weak with a number of differences between the manual records we requested the care homes maintain and the registered results data. This looks like it may be impacted by the 2-stage registration process whereby both the visitor is required to register, and the care home is required to upload the result. For a number of visitors, the 2-stage registration process does not appear to have been completed correctly with the visitor-initiated registration process being problematic for the visitor often due to the IT literacy of the visitor

For the homes in the pilot who used PCR testing, a number of user experience challenges were identified. Some visitors struggled to complete PCR testing at home and it involved additional staff time to manage organisation of visits. One care manager received void PCR test results from 2 separate visitors, so visitors had to delay their visit. It was hypothesised that some PCR visitors were also delaying being tested due to uncertainties around when result would arrive.

A full pilot evaluation report will be published shortly. In light of the clinical evidence and the learning from the pilot, we have made adjustments to our guidance and webinar training including:

- producing user friendly guidance aimed specifically at visitors to support care homes to help their visitors understand the process, including a letter to visitors, pictorial guidance, and a video for visitors
- updating our digital registration journey to make this as user friendly and simple as possible
- communicating to all care homes to only begin testing once they have a way to register results so that we are able to track results and compare these against outbreak data
- publishing our clinical standard operating procedure (SOP), including clinical process for testing and a full risk register
- running daily webinars for all care homes, including an interactive Q&A to support care homes to prepare for visitor testing, answer all questions, including clinical, and emphasise key safety messages

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